

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**20-280/S-031**

**CHEMISTRY REVIEW(S)**

**CHEMIST'S REVIEW**

<b>1. ORGANIZATION CDER/HFD-510</b> Division of Metabolism and Endocrine Drug Products		<b>2. NDA # 20280</b>	
<b>3. NAME AND ADDRESS OF APPLICANT</b> Pharmacia & Upjohn Company 7000, Portage road, Kalamazoo, MI 49001, Phone: ((616) 833-6717		<b>4. SUPPLEMENT : SE1-031</b> Doc. Date: 25 <sup>th</sup> -Jan-2001      Rec. date: 26 <sup>th</sup> -Jan-2001	
		<b>5. NAME OF THE DRUG : Genotropin</b>	
		<b>6. Nonproprietary Name :</b> Somatropin[rDNA] for Injection	
<b>7. SUPPLEMENT PROVIDES</b> for long term treatment of growth failure in children born small for gestational age(SGA)		<b>8. AMENDMENT -N/A</b>	
<b>9. PHARMACOLOGICAL CATEGORY</b> Growth hormone replacement therapy in adults and long term treatment of children who have growth failure.	<b>10. HOW DISPENSED</b>	<b>11. RELATED -N. A. -</b>	
<b>12. DOSAGE FORM:</b> subcutaneous injection	<b>13. POTENCY :</b> 1.3 mg/mL(4 IU/mL), 5.0 mg/mL (15 IU/m), 12 mg/mL (36 IU/mL)		
<b>14. CHEMICAL NAME AND STRUCTURE</b>  Genotropin(Somatropin [rDNA] origin			
<b>15. COMMENTS :</b> This NDA #20280 supplement 031 is an efficacy supplement. The sponsor has originally submitted this supplement on 30 <sup>th</sup> June 2000, which was withdrawn, based on clinical issues. This is a resubmission.			
<b>16. CONCLUSIONS AND RECOMMENDATIONS</b> The information provided by the sponsor has been reviewed. The sponsor has claimed a categorical exclusion from environmental assessment requirement. <b>SATISFACTORY</b>			
<b>17. REVIEWER NAME (AND SIGNATURE)</b> Pardha Komanduri		<b>DATE COMPLETED :</b> 16 <sup>th</sup> -JULY-2001	
<b>R/D INITIALED BY</b>			
<b>DISTRIBUTION:</b> <b>Original:</b> NDA 20280 <b>cc:</b> HFD-510 Division File/ Moore S/ King C/Pardha K			

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### **ITEM 3.3 CHEMISTRY, MANUFACTURING, AND CONTROLS SUMMARY**

GENOTROPIN® (somatropin [rDNA origin] for injection) is manufactured in Stockholm, Sweden. GENOTROPIN is approved in the following presentations:

- Two-chamber cartridges at strengths of 1.5 mg (without preservative), 5.8 mg (with preservative), and 13.8 mg (with preservative).
- GENOTROPIN MINIQUICK® Growth Hormone Deliver Device containing a 2-chamber cartridge of GENOTROPIN (without preservative) at strengths of 0.2, 0.4, 0.6, 0.8, 1.0, 1.2, 1.4, 1.6, 1.8, and 2.0 mg.

A complete summary of the chemistry, manufacturing, and controls (CMC) of somatropin was included in NDA 20-280.

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